APPENDIX 3

Comments Regarding EPA 402-F-93-004, July 1993 [released in final form September 1993] "Secondhand Smoke: What You Can Do About Secondhand Smoke As Parents, Decisionmakers, and Building Occupants"

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COMMENTS REGARDING

EPA 402-F-93-004, July 1993

[released in final form September 1993]

"SECONDHAND SMOKE: WHAT YOU CAN DO ABOUT SECONDHAND SMOKE AS PARENTS, DECISIONMAKERS, AND BUILDING OCCUPANTS"

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WHAT IS ENVIRONMENTAL TOBACCO SMOKE?

EPA Claims: "Secondhand" smoke "contains more than 4,000 substances, more than 40 of which are known to cause cancer in humans or animals and many of which are strong irritants."

Response:

- Animal inhalation experiments using fresh or aged sidestream smoke or constituents of sidestream smoke do not support the claim that ETS causes cancer of the lung.

  To date, all three publicly available animal inhalation studies have reported no statistically significant increased incidence of tumors in animals exposed to ETS compared with control animals.[1-4]

- Moreover, none of the lifetime, "whole smoke" exposure studies on animals, originally designed to assess possible biological effects from mainstream smoke exposures, have reported the induction of lung carcinomas via inhalation.

- Recent reviews of the literature on suspected pulmonary carcinogens have concluded that none of the individual

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constituents in sidestream smoke that is classified as potentially carcinogenic has been found to induce pulmonary cancer via inhalation in experimental animals.

The "carcinogenic agents" supposedly identified in tobacco smoke either are not suspected pulmonary carcinogens, or have not been unequivocally demonstrated as tumorigenic to human tissue or to the lung tissue of experimental animals.[5-7]

- Positive results reported for skin painting, intratracheal implantation or subcutaneous application in animals are of questionable relevance to the mode of exposure (inhalation) for ETS.

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ETS EXPOSURE AND LUNG CANCER IN NONSMOKERS

EPA Claims: "Secondhand smoke has been classified by the U.S. Environmental Protection Agency (EPA) as a known cause of lung cancer in humans (Group A carcinogen)."

"Passive smoking is estimated by EPA to cause approximately 3,000 lung cancer deaths in nonsmokers each year."

Response:

- The claim of 3,000 deaths purportedly due to ETS exposure is derived from a risk assessment on ETS conducted by the U.S. Environmental Protection Agency. The risk assessment was based upon a statistical review, called "meta-analysis," of epidemiologic studies of nonsmoking women married to smokers.

- The meta-analysis conducted by EPA used 11 spousal smoking studies conducted in the United States.[1-11] Not one of these studies originally reported a statistically significant overall risk estimate.

  Indeed, even when the EPA lowered the statistical confidence limits reported for the U.S. studies from the standard 95% to

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90%, all but one of the 11 studies individually failed to achieve statistical significance.[5]

Nevertheless, EPA used these studies to arrive at the conclusion that ETS exposure is associated with an increased risk of lung cancer.

- The EPA failed to include in its meta-analysis relevant data from two recent, major U.S. studies on ETS.[12,13] These two studies appeared in the scientific literature months prior to the release of the Risk Assessment.

The inclusion of both the studies in the meta-analysis should negate the classification of ETS as a Group A carcinogen, in that a cumulative risk estimate for the U.S. studies would not be statistically significant, even at the 90% confidence interval.14 The Agency should have estimated no statistically significant increased risk for lung cancer, at either a 95% or a 90% confidence interval.

- A critical flaw of the EPA's meta-analysis is that it did not aggregate similar data. For example, all of the studies employed different questionnaires and different assessments of past exposure; five of the tudies failed o match cases with controls; and the crite a for control selection were

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different in each study.[15]

EPA has not addressed the issue of the aggregation of dissimilar data in its meta-analysis. Moreover, even the "common thread" identified by the EPA as justification for meta-analysis, spousal smoking, is defined differently across studies.

- Furthermore, EPA reviewed a total of 30 epidemiologic studies in the risk assessment.[1-11,16-34] Of these, 24 reported no statistically significant overall risk estimate, meaning that those data are compatible with the hypothesis that there is no overall association between spousal smoking and lung cancer.

Even positive point estimates (greater than 1.00) that do not achieve statistical significance are compatible with the null hypothesis of "no association" between spousal smoking and lung cancer. Reported overall point estimates in six non-U.S. studies are statistically significant, but the EPA did not ascertain whether or not these purported associations are due to some feature that is coincidental to "marriage to a smoker" (e.g., common diet, occupational exposures, socio-economic status and other lifestyle characteristics).

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- During the course of the development of the risk assessment, numerous critical scientific comments were provided to the Agency. For instance, more than 100 public comments were submitted on the first public draft of the risk assessment, in 1990. An EPA consultant involved in the risk assessment characterized the majority of the comments as "quite lengthy, detailed, and highly critical."

- Many of the points raised in the public comments in 1990, and in additional public comments provided to EPA in 1992, were not adequately addressed by the Agency before the risk assessment was finalized. For instance, a meta-analysis incorporating the two new United States studies was submitted to the Executive Committee of the EPA's Science Advisory Board; it yielded a summary risk estimate that was not statistically significant.[14] Nevertheless, the risk assessment was finalized without taking into account these new data.

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ETS EXPOSURE AND CHILDHOOD RESPIRATORY CONDITIONS

EPA Claims: "The developing lungs of young children are also affected by exposure to secondhand smoke."

"EPA estimates that passive smoking is responsible for between 150,000 and 300,000 lower respiratory tract infections in infants and children under 18 months of age annually, resulting in between 7,500 and 15,000 hospitalizations each year."

Response:

- A 1988 review of 30 of the major studies on parental smoking noted that while several studies of adequate scientific design reported an association between reported parental smoking and childhood respiratory conditions, "most studies had significant design problems that prevent reliance on their conclusions." The authors concluded that "many questions remain, and future studies should consider important methodological standards to determine more accurately the effect of passive smoking on child health."[1]

- The studies on childhood respiratory disease and parental smoking suffer from numerous methodological problems. In the

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majority of studies, exposure to ETS is estimated by questionnaire responses from parents. Therefore, there are no quantitative data on the actual exposure levels of children in these studies. Also, important confounding variables are not consistently controlled for in the studies of parental smoking. Not surprisingly, the studies have reported conflicting and inconsistent findings.

- The reliability of lung function tests in the studies of parental smoking and children's lung function has been debated in the scientific literature. In 1982, a United States research group showed that a comparison of body size with lung function eliminated any reported correlation between parental smoking and children's lung function.[2] The magnitude of pulmonary function changes reportedly associated with parental smoking is so small that researchers are unsure of any clinical significance of the reported decrements.

- After reviewing the literature on parental smoking and pulmonary function in children, researchers in 1992 asserted that the reported decrements in pulmonary function were, "with few exceptions," small and that all of the values were still within the normal range.[3]

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ETS EXPOSURE AND OTITIS MEDIA

EPA Claim: "Passive smoking can lead to a buildup of fluid in the middle ear, the most common cause of hospitalization of children for an operation."

Response:

- A 1992 review of the epidemiological literature reported that only six of the 17 major studies on middle ear disease and parental smoking reported a statistically significant association.[1]

- Several recent studies provide additional support for the argument that parental smoking is not associated with an increased risk of otitis media in children.[2-5]

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ETS EXPOSURE AND ASTHMA IN CHILDREN

EPA Claims: "Asthmatic children are especially at risk. EPA estimates that exposure to secondhand smoke increases the number of episodes and severity of symptoms in hundreds of thousands of asthmatic children. EPA estimates that between 200,000 and 1,000,000 asthmatic children have their condition made worse by exposure to secondhand smoke. Passive smoking may also cause thousands of non-asthmatic children to develop the condition each year."

Response:

- The EPA Risk Assessment concedes that "the epidemiologic evidence is suggestive <u>but not conclusive</u> that ETS exposure increases the number of new cases of asthma in children who have not previously exhibited symptoms." (page 1-5) [emphasis added]

- Only five of 21 major studies on asthma in children and parental smoking have reported a statistically significant association.[1]

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- The parental smoking studies on childhood asthma report inconsistent conclusions and suffer from several important methodological problems, such as inaccurate exposure assessment and inadequate treatment of potential confounding factors. The studies differ in their data collection methods and in their definitions of asthma.

- Researchers have identified a number of environmental and social factors that may potentially play a role in childhood asthma. These include house dust, house dust mites, grass pollens, cockroach allergens, diet, damp housing, emotional incidents, family dysfunction, and other sources of stress.[2-5]

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ETS EXPOSURE AND CLAIMS OF IRRITATION AND ANNOYANCE

EPA Claims: "Exposure to secondhand smoke causes irritation of the eye, nose, and throat."

Responses:

- Persons may report "discomfort" or "annoyance" that they attribute to ETS exposure. However, subjective perceptions are difficult to evaluate.

- The existence of allergens in tobacco smoke has not been established conclusively.[1-3] Claims of annoyance and emotional responses should not be confused with genuine allergic reactions.

- A vast range of substances contribute to indoor air quality (IAQ). Singling out ETS for particular attention overlooks these other substances. Personal perceptions of comfort may be related to air temperature, relative humidity, lighting, and/or the presence of biological and chemical substances in the air.

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ETS EXPOSURE AND ADULT RESPIRATORY CONDITIONS

EPA Claims: "Passive smoking can also irritate the lungs, leading to coughing, excess phlegm, chest discomfort, and reduced lung function."

Responses:

- The U.S. Surgeon General, in the 1986 report on ETS, concluded that the magnitude of the reported lung function decrements in nonsmoking adults exposed to ETS were "quite small, even at moderate to high exposure levels" and that "it is unlikely that this change in airflow, per se, results in symptoms."[1]

- Regarding cough, phlegm and wheezing in adult nonsmokers, the Surgeon General reported that "few studies have addressed the relationship of chronic respiratory symptoms in nonsmoking adults with environmental tobacco smoke exposure." The Surgeon General reported on two studies (Schilling 1977; and Schenker 1982). Neither study reported an association between spousal smoking and an increased incidence of respiratory symptoms in nonsmoking women.

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- The authors of the EPA risk assessment on ETS concede that the studies on ETS and adult respiratory health are "inconsistent and sometimes contradictory."

- Several literature reviews on ETS and adult respiratory health (not addressed in the EPA risk assessment) have contradicted the claim that ETS exposure is associated with respiratory symptoms in nonsmoking adults. For example, a review by Laurent, et al., (1989) suggested that the purported long-term health effects from exposure to ETS are difficult to demonstrate in healthy adults and that the results of the epidemiological studies are "sometimes conflicting and often open to question." In a 1990 review, Witorsch noted that, in addition to "all of the problems" with the studies, "these results are too variable to permit any conclusion of association."

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ETS EXPOSURE AND CARDIOVASCULAR DISEASE

EPA Claims: "Secondhand smoke may affect the cardiovascular system, and some studies have linked exposure to secondhand smoke with the onset of chest pain."

Response:

- Although there are 12 epidemiological studies on a possible association between ETS and heart disease, in most of these, the data were not reported to be statistically significant.

  All of the studies suffer from a variety of serious methodological weaknesses including small sample sizes, misclassification of smoking status of study participants, inadequate assessment of ETS exposure, failure to control adequately for potential confounding variables and failure to confirm causes of death.

- These weaknesses in the data were emphasized in the 1986 Surgeon General's Report which judged that "no firm conclusion" could be made regarding a possible relationship between ETS and heart disease.[1] A 1986 report from the National Academy of Sciences (NAS) reached a similar conclusion.[2]

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- A review of the literature on ETS and heart disease was published in 1991 by the former director of toxicology of a major European research laboratory. In it, he described the scientific data relating to a possible heart disease risk in nonsmokers exposed to ETS as "not very convincing."[3]

- The claim about the onset of chest pain (angina) is largely based on a 1978 study involving 10 heart patients which reported that exposure to tobacco smoke could hasten the onset of heart pain during exercise.[4]

However, the credibility of this report, as well as other research by this investigator, has been widely challenged.[5]

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ETS IN THE HOME

EPA Claims: "Don't smoke in your house or permit others to do so."

"If a family member insists on smoking indoors, increase ventilation in the area where smoking takes place. Open windows or use exhaust fans."

"Do not smoke if children are present, particularly infants or toddlers. They are particularly susceptible to the effects of passive smoking."

"Don't allow baby-sitters or others who work in your home to smoke in the house or near your children."

Response:

- The decision to smoke should be a personal one, as should be the decision to smoke or to allow smoking in one's home.

- Assuring adequate ventilation in the home is important, not only if smoking takes place, but to minimize levels of

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substances such as nitrogen dioxide from gas stoves, that can contribute to indoor air quality.

- Parents should make their own personal decisions about whether certain activities, including smoking, should be carried out in the presence of their children.

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SMOKING "WHERE CHILDREN SPEND TIME"

EPA Claims: "EPA recommends that every organization dealing with children have a smoking policy that effectively protects children from exposure to environmental tobacco smoke."

"Help parents understand the serious health risks to children from secondhand smoke. Work . . . to make your child's environment smoke free."

Response:

- Parents are in the best position to make their own decisions as to whether activities including smoking are to be conducted in the presence of their children.

- Numerous factors, including gas stove use, day-care attendance, dust mites, and pets, may contribute to childhood respiratory conditions. Singling out ETS for particular attention overlooks all these important factors.

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WORKPLACE SMOKING ISSUES

EPA Claims: "Simply separating smokers and nonsmokers within the same area, such as a cafeteria, may reduce exposure, but nonsmokers will still be exposed to recirculated smoke or smoke drifting into nonsmoking areas."

"Prohibiting smoking indoors or limiting smoking to rooms that have been specially designed to prevent smoke from escaping to other areas of the building are the two options that will effectively protect nonsmokers."

"Air from the smoking room should be directly exhausted to the outside by an exhaust fan. Air from the smoking room should not be recirculated to other parts of the building. More air should be exhausted from the room than is supplied to it to make sure ETS doesn't drift to surrounding spaces."

Response:

- While some have claimed that simple separation of smokers and nonsmokers is not effective, numerous studies in the

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scientific literature report that simple separation of smokers and nonsmokers in the workplace, even under conditions of recirculation, can effectively minimize nonsmoker exposures to ETS.[1-12]

Moreover, the data suggest that bans and separately ventilated smoking areas do not result in significant reductions of ETS exposures beyond adequate ventilation and/or the simple separation of smokers and nonsmokers under a common ventilation system.

- IAQ measurements taken under normal, everyday conditions indicate that the contribution of tobacco smoke to the ambient air in typical public places and workplaces is minimal.[13-16]

- For example, some studies report typical nicotine measurements ranging from an exposure equivalent of 1/100 to 1/1000 of filter cigarette per hour.[17-23] That means a nonsmoker would have to spend from 100 to 1000 hours in an office, restaurant or other public place in order to be exposed to the nicotine equivalent of a single cigarette.

- Because it is visible and easily identified by its aroma, tobacco smoke is often blamed for poor indoor air quality. Government and private studies of "sick buildings" in the

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United States and Canada report, however, that tobacco smoke is related to only two percent to five percent of the buildings investigated for complaints about air quality.[24-30] This suggests that even a total smoking ban is not likely to affect comfort problems in 95 to 98 percent of "sick buildings."[31]

- Th majority of indoor air quality problems in "sick buildings" have been traced to inadequate fresh air and poor air filtration. Because the visibility of tobacco smoke may be an indicator of inadequate ventilation, the prohibition of smoking often serves to mask the real reason for poor indoor air quality -- lack of proper ventilation. In addition, concentrating on tobacco smoke ignores the fact that adequate ventilation should always be provided in any enclosed space, regardless of whether or not smoking is permitted.

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SMOKING IN RESTAURANTS AND BARS

EPA Claims: "Some communities have banned smoking in places such as restaurants entirely. Others require separate smoking areas in restaurants, although most rely on simply separating smokers and nonsmokers within the same space, which may reduce but not eliminate involuntary exposure to ETS."

Response:

- While some have claimed that simple separation of smokers and nonsmokers is not effective, numerous studies in the scientific literature report that simple separation of smokers and nonsmokers, even under conditions of recirculation, can effectively minimize nonsmoker exposures to ETS.[1-12]

- The scientific literature includes a number of studies measuring indoor air quality in restaurants, bars and other public places. These studies indicate that nonsmoker exposure to ETS under normal, everyday conditions is minimal.[13-16]

- Studies reported in the scientific literature contain data regarding the low levels of ETS constituents purportedly "transferred" from smoking to nonsmoking areas, even under

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conditions involving a shared ventilation (recirculation) system. Data reported in those studies indicate that ETS constituents, and particularly nicotine, RSP, and CO in nonsmoking areas in buildings where smoking is permitted, are often only slightly above the limits of detection, and often indistinguishable from the "background" levels of constituents that can be found in the air of buildings in which smoking is prohibited.

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EVEN EPA ACKNOWLEDGES THAT IT HAS NO REGULATORY AUTHORITY OVER ETS

EPA Claims: EPA "recommends" that companies and organizations "dealing with children" have smoking policies.

Response:

- These statements are indeed recommendations. EPA has no authority to regulate ETS or indoor air quality.

- Former EPA Administrator William K. Reilly acknowledged EPA's lack of regulatory authority over ETS in a January 7, 1993, press conference to announce the release of EPA's risk assessment on ETS.[1]

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